



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 12, 2006

MEMORANDUM TO: C. William Reamer, Director
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety
and Safeguards

FROM: Jack D. Parrott, Senior On-Site Licensing Representative */RA/*
Project Management, Section A
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety
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Division of Nuclear Material Safety, Region IV

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ON-SITE LICENSING
REPRESENTATIVES' REPORT ON THE YUCCA MOUNTAIN
PROJECT, FOR JANUARY 1, 2006, THROUGH MARCH 31, 2006

The purpose of this memorandum is to transmit the U.S. Nuclear Regulatory Commission (NRC) On-Site Representatives' (ORs') quarterly report for the period of January 1, 2006, through March 31, 2006.

This report highlights a number of Yucca Mountain Project activities of potential interest to NRC staff. The ORs' continue to respond to requests from NRC Headquarters staff to provide various documentation and feedback related to Key Technical Issues (KTIs) and their resolution. During this reporting period, the ORs' continued to observe matters associated with Yucca Mountain Site activities, KTIs, and audits. The ORs' also attended various meetings and accompanied NRC staff on visits to Yucca Mountain.

In accordance with 10 CFR 2.390 of NRC's "Rules of General Applicability," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records' component of NRC's document system, "Agencywide Document Access and Management System" (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions about his report or its attachments, please call Jack D. Parrott, on (702) 794-5047, or Robert M. Latta, on (702) 794-5048.

Enclosure(s):

1. "U.S. Nuclear Regulatory Commission On-Site Licensing Representatives' Report Number OR-06-01, for the Reporting Period of January 1, 2006, through March 31, 2006"
2. Table 1: "U.S. NRC On-Site Licensing Representatives' Tracking Report for Open Items Followed in Quarterly OR Report"

cc: See attached list.

Memorandum to C.William Reamer, Director, from J. Parrott, and R. Latta, dated: June 12, 2006
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ON-SITE LICENSING REPRESENTATIVES' REPORT
NUMBER OR-06-06,
FOR THE REPORTING PERIOD OF
JANUARY 1, 2006, THROUGH MARCH 31, 2006**

Enclosure 1

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ACRONYMS AND ABBREVIATIONS

ACRO	MEANING
ADAMS	Agencywide Documents Access and Management System
AOI	Audit Observation Inquiries
BSC	Bechtel SAIC Company, LLC
CAP	Corrective Action Program
CNWRA	Center for Nuclear Waste Regulatory Analyses
CR	Condition Report
DOE	U.S. Department of Energy
HLWRS	High-Level Waste Repository Safety
INFIL	Infiltration Model
INL	Idaho National Laboratory
IPRT	Integrated Product Review Team
KTI	Key Technical Issue
LA	License Application
LBT	Large Block Test
MOA	Memorandum of Agreement
NOAA	National Oceanic and Atmospheric Administration
NRC	U.S. Nuclear Regulatory Commission
NTS	Nevada Test Site
NWTRB	Nuclear Waste Technical Review Board
OQA	Office of Quality Assurance
OR	On-Site Representative
PA	Performance Assessment
PCSA	Pre-closure Safety Analysis
QA	Quality Assurance
QARD	Quality Assurance Requirements Description
QRM	QARD Requirements Matrix
RIV	Region IV

SNL	Sandia National Laboratory
TWP	Technical Work Plan
USGS	U. S. Geological Survey
YMP	Yucca Mountain Project

EXECUTIVE SUMMARY

SITE ACTIVITIES AND DATA ACQUISITION

On February 13, 2006, NRC and Center staff, including an On-Site Representative (OR), visited the Fran Ridge Large Block Test (LBT) facility at the Yucca Mountain site. The Department of Energy (DOE) is currently planning to decommission the LBT to use the site for other purposes.

QUALITY ASSURANCE (QA) AND ENGINEERING

Observation of Surveillance of Infiltration Model (INFIL) Software Evaluation and Qualification Process

From January 16 to 24, 2006, an OR observed portions of the DOE's Office of Quality Assurance (OQA) compliance-based surveillance of the adequacy of the INFIL, Version 2.0, software evaluation process, initiated by Idaho National Laboratory, and baseline documentation for the revised INFIL Version 2.1 software qualification. The overall results of the surveillance were satisfactory, as determined by DOE. The OR determined that this oversight activity was adequately performed. No audit observation inquiries (AOIs) were identified.

Observation of Surveillance of Existing Data Used in INFIL

From January 17 to February 13, 2006, an OR observed OQA's surveillance of Bechtel SAIC Company, LLC's (BSC's) efforts to verify the quality of the data used in past infiltration modeling. These data inputs served as the basis of the U.S. Geological Survey INFIL work done for the Project.

The DOE surveillance determined that the data inputs supporting the original INFIL work were thoroughly reviewed. The OR determined that this surveillance activity was adequately performed. No AOIs were identified.

Observation of Surveillance of Sandia National Laboratory (SNL)

From March 7 to March 9, 2006, ORs observed OQA's compliance based surveillance (OQA-SI-06-010) of the adequacy of the documentation developed for the creation of a replacement infiltration model being performed by SNL. The surveillance team determined that SNL is adequately and effectively implementing the program for QA compliance in the development of a replacement INFIL and that compliance with the QA procedures reviewed was satisfactory. The ORs determined that this oversight activity was adequately performed. No AOI's were identified.

Observation of Surveillance of New Data Used in Infiltration Model

On January 17-18, 2006, assigned OR staff member observed BSC's QA organization's surveillance of the INFIL model data development and qualification activities. The purpose of this surveillance (BQA-SI-06-018), was to evaluate the data development and qualification efforts for LandSat vegetation and National Oceanic and Atmospheric Administration precipitation data that will be used in DOE's new INFIL. As a result of this activity, the BSC surveillance team determined that the data extraction and analysis processes were under development, with completion expected in late spring. No AOIs were identified, and the NRC observers determined that this oversight activity was effectively performed.

Requirements Flow-Down and Procedural Adequacy Audit Observation

During this reporting period, the ORs observed the conduct of DOE's OQA Audit (OQA-BSC-06-07) of BSC's procedure adequacy and flow-down of QA requirements. The purpose of this audit was to confirm the adequate incorporation of requirements into implementing procedures, before DOE's rescinding the suspension of BSC's approval for affected Design Engineering and Pre-Closure Safety Analysis technical products. As a result of these evaluations, the audit team concluded that although the selected procedures generally implemented the requirements contained in the Quality Assurance Requirements Description, BSC's process for incorporating requirements into implementing procedures was indeterminate, pending revision of the QARD Requirements Matrix (QRM). Based on the results of this audit, the ORs determined that this oversight activity was well-planned and effectively performed. However, one weakness was identified concerning the failure of BSC's Organizational Assurance group to ensure that the necessary documentation to support this quality-affecting activity was available for the audit team's review. The ORs also identified two Open Items that were provided to the Audit Team Leader at audit conclusion.

OR Interactions on Yucca Mountain Project (YMP) Design Control Topical Area

During February and March 2006, assigned OR staff reviewed the current YMP design control program and the planned actions to improve this area. This OR interaction was to verify that DOE has identified the correct problems, and is addressing appropriate corrective actions in this area. The Integrated Product Review Team, Condition Reports (CRs), and other assessments identified many important and appropriate actions and recommendations for improving design-control and requirements-management processes, and indicated a proper integrated approach across project management and technical disciplines. NRC will continue to review DOE's actions, to develop an organizational structure and managerial approach that can identify, recognize, and to promptly address developing regulatory or technical issues, before they become major problems.

REPORT DETAILS

INTRODUCTION

The principal purpose of the On-Site Representatives' (ORs') report is to inform U.S. Nuclear Regulatory Commission (NRC) managers, staff, and contractors about information, on the U.S. Department of Energy's (DOE's) programs, in repository design, performance assessment (PA), performance confirmation, and environmental studies, that may be useful in fulfilling NRC's role during prelicensing consultation. The primary focus of this and future OR reports will be on DOE's programs for subsurface and surface-based testing, PA, data management systems, environmental studies, and quality assurance (QA). Relevant information includes new technical data, DOE's plans and schedules, and the status of activities to support preparation of the License Application (LA). The ORs also take part in activities associated with resolving NRC Key Technical Issues (KTIs).

This report covers the period of January 1, 2006, through March 31, 2006.

OBJECTIVES

The ORs' primary missions are to act as points of prompt information exchange, and to identify preliminary concerns with site investigations and potential licensing issues. The ORs carry out these roles by gathering and evaluating information, identifying concerns, and bringing more significant issues to NRC management's attention. Communication with DOE is accomplished by exchanging information on data, plans, schedules, documents, activities and pending actions, and resolution of issues. With input from NRC Headquarter's management, the ORs interact with DOE scientists, engineers, and managers on the implementation of NRC policies, programs, and regulations. The ORs also focus on issues such as design controls, data management systems, PA, and KTI resolution. A primary OR role is to identify areas, whether in site studies, activities, or procedures, that may be of interest or concern to the NRC staff.

1. SITE ACTIVITIES AND DATA ACQUISITION

On February 13, 2006, NRC staff, Center for Nuclear Waste Regulatory Analyses (CNWRA) staff and an OR visited the Fran Ridge Large Block Test (LBT) facility, at the Yucca Mountain site, which is a 36-cubic-meter (non-metric) block carved out of the Topopah Spring Tuff. DOE used the block for fracture mapping, flow, seepage, and transport experiments. It is currently planning to decommission the LBT, to use the site for other purposes. Staff is evaluating whether the LBT facility could be used for validating NRC's computer simulation models.

2. OUTREACH ACTIVITIES

N/A - this reporting period.

3. QA and ENGINEERING

3.1 Observation of Surveillance of Infiltration Model (INFIL) Software Evaluation and Qualification Process

From January 16 to 24, 2006, an OR observed portions of DOE's Office of Quality Assurance's (OQA's) compliance-based surveillance, OQA-SI-06-009, of the adequacy of the INFIL, Version 2.0, software evaluation process, initiated by Idaho National Laboratory (INL), and baseline documentation for the revised INFIL Version 2.1 software qualification. The requirements for the surveillance were based in part on the technical work plan (TWP) for the "Infiltration Model Assessment, Revision, and Analyses of Downstream Impacts," TWP-NBS-HS-000012. This TWP is being implemented to assess, revise, and analyze the impacts to downstream models from work associated with the development, by the U.S. Geological Survey (USGS), of site-specific infiltration estimates for Yucca Mountain. The stated goal of this activity is to restore credibility, traceability, and transparency to the infiltration work, and to reestablish confidence in the infiltration model, before submittal of the LA, to NRC, for a geologic repository for high-level waste at Yucca Mountain.

The scope of the surveillance included a review of software documentation packages, to assess the adequacy of the INFIL Version 2.0 software evaluation process, initiated by INL, for proper technical use and software life-cycle development. The scope also included assessing the adequacy of the (at that time incomplete) baseline documentation for the revised INFIL Version 2.1 software qualification. The conclusion of the DOE surveillance team was that staff members working on the INFIL software evaluation and revision were qualified for their assigned tasks and that they complied with current software procedures. No adverse conditions and opportunities for improvement were initiated as a result of this surveillance. The overall results of the surveillance were satisfactory, as determined by DOE. The OR determined that this oversight activity was adequately performed. No AOs were identified.

Subsequent to this surveillance, the INFIL Version 2.1 software was baselined (put under configuration management control). However, model sensitivity runs conducted subsequent to baselining revealed two software problems that were identified in Condition Report (CR)-7587. These conditions are being addressed in INFIL Version 2.2. Version 2.2 of the INFIL code had not yet been baselined as of the end of the reporting period.

3.2 Observation of Surveillance of Data Used in INFIL

From January 17 to February 13, 2006, an OR observed OQA's surveillance of Bechtel SAIC Company, LLC's (BSC's) efforts to verify the quality of the data used in past infiltration modeling. These data inputs served as the basis of the USGS INFIL work done for the Project. The scope of the surveillance (OQA-SI-06-008) was to assess the effectiveness of BSC data management controls, to ensure that data inputs feeding the original infiltration Analysis and Model report, MDL-NBS-HS-000023, Revision 00, *Simulation of Net Infiltration for Present-Day and Potential Future Climates*, were adequately reviewed and verified as meeting applicable quality requirements. In addition, two data qualification efforts for data identified by BSC as required for future infiltration modeling work were also assessed.

The surveillance team determined that the data inputs supporting the original INFIL work, which were documented in MDL-NBS-HS-000023, were thoroughly reviewed. The BSC surveillance team believe that these reviews, and related follow-on actions, significantly enhanced the accuracy, transparency, and traceability of the data inputs, and that the level of scrutiny and rigor applied to this effort was satisfactory and effective.

The OR determined that this surveillance activity was adequately performed and that the adverse conditions and opportunities for improvement found by the surveillance were appropriately documented in the Project's Corrective Action Program (CAP). No AOIs were identified.

3.3 Observation of Surveillance of Sandia National Laboratory (SNL)

From March 7 to March 9, 2006, the ORs observed OQA's compliance-based surveillance (OQA-SI-06-010) of the adequacy of the documentation developed for the creation of a replacement INFIL that SNL was undertaking. The replacement INFIL is based on a conceptual model similar to that in MDL-NBS-HS-000023, Revision 1, *Simulation of Net Infiltration for Present-Day and Potential Future Climates*. The DOE surveillance team reviewed: (a) qualification and training of personnel, including subcontractors; (b) planning; (c) informal model checking and review documentation; (d) procurement documents to subcontractors; (e) software; (f) scientific notebooks; (g) draft model development documentation; (h) data submittals; (i) QA records; and (j) electronic data controls.

The DOE surveillance team determined that SNL is adequately and effectively implementing the program for QA compliance in the development of a replacement INFIL. Compliance to the QA procedures reviewed was satisfactory. No adverse conditions and opportunities for improvement were initiated by DOE as a result of this surveillance. The overall results of the surveillance were satisfactory, as determined by DOE. The ORs determined that this oversight activity was adequately performed. No AOIs were identified.

3.4 Observation of INFIL Surveillance

On January 17-18, 2006, assigned OR staff participated in a surveillance performed by BSC QA organization. The purpose of this surveillance was to evaluate the data development and qualification efforts for LandSat vegetation and National Oceanic and Atmospheric Administration (NOAA) precipitation data that will be used in DOE's new INFIL. This INFIL will be one of the principal technical products used to support the potential Yucca Mountain Repository LA.

During the performance of this oversight activity, the BSC surveillance team interviewed the technical staff performing the work, examined data and software qualification methods, and reviewed record-keeping and document-control processes. The BSC surveillance team also evaluated work products to establish compliance with requirements for submitting data to the Technical Data Management System, and controls for the qualification of unqualified data. As a result of these reviews, the BSC surveillance team determined that the data extraction and analysis processes were

under development, with completion expected in late spring. The surveillance team also noted that although scientific notebooks were not being used as a record of these activities, adequate implementing controls had been established.

The ORs determined that his oversight activity was adequately performed. No AOIs were identified.

3.5 Requirements Flow-Down and Procedural Adequacy Audit Observation

As previously documented in OR Report 05-05, dated February 6, 2006, NRC had determined that DOE's administration of the CAP had not been effective in: (i) eliminating the repeated identification of deficiencies related to requirements management and design control; (ii) identifying and resolving adverse trends concerning these issues; and (iii) initiating the actions necessary to identify and appropriately address the root-cause of these issues. Subsequent to the identification of these discrepancies, DOE acknowledged, during the December 7, 2005, NRC/DOE Management Meeting, that, as a result of the root-cause analysis for CR 6278, and information related to internal evaluations, DOE had determined that the Project had not maintained nor properly implemented its requirements management system. As a result of these deficiencies, DOE identified proposed corrective actions, which included the suspension of approval of all Design Engineering and Pre-Closure Safety Analysis (PCSA) technical products subject to Quality Assurance Requirements Description (QARD) requirements. To facilitate the corrective action process, DOE also developed an Integrated Product Review Team (IPRT) action plan that included the performance of a compliance audit of BSC. The purpose of this audit was to confirm the adequate incorporation of QARD requirements into implementing procedures before rescinding the suspension of approval for affected Design Engineering and PCSA technical products.

From March 13 through 22, 2006, the ORs observed the conduct of DOE's OQA Audit of BSC's procedure adequacy and flow-down of QA requirements, performed in response to the IPRT action plan. Specifically, OQA reviewed the adequacy of QA requirements flow-down from the project's QARD document to selected procedures implemented by BSC's Design & Engineering, Licensing & Nuclear Safety, and the PCSA organizations. The audit team also evaluated the effectiveness of corrective actions for previous CRs related to requirements flow-down and procedural adequacy.

To confirm the adequate incorporation of QA requirements into implementing procedures, the audit team developed detailed checklists to address the elements contained in QARD Sections 2.0, "Quality Assurance Program;" 3.0, "Design Control;" 5.0, "Implementing Documents;" 6.0 "Document Control;" and Supplement III, "Scientific Investigation." The audit team effectively used these checklists to determine if: (1) the selected procedures contained the necessary process steps to implement the related QARD requirements; (2) the procedural steps established a logical progression of activities; and (3) the procedures were transparent in referencing appropriate documents. The audit team also used the information in BSC's Requirement Management System, a non-quality affecting database, which links the QARD requirements to the implementing mechanisms, to trace requirements to the respective procedures.

As a result of these evaluations, the DOE audit team concluded that the selected

procedures adequately implemented the QARD requirements, with one notable exception. Specifically, the audit team identified deficiencies related to procedure LP-2.15Q-BSC, "Managing Requirements," that did not incorporate the necessary process steps to implement QARD requirements. The DOE audit team also concluded that the process for incorporating requirements into implementing procedures was "indeterminate," because BSC was not continuously updating the QARD Requirements Matrix (QRM), which is the QA document that serves as a record of compliance with the requirements of the QARD. As noted by DOE QA, a follow-up oversight activity is anticipated to resolve this "indeterminate" condition.

Based on the results of this audit, the ORs determined that this oversight activity was well-planned and effectively performed. However, as noted above, the audit team was not able to verify the effectiveness of the requirements flow-down process because the QRM had not been revised to reflect the numerous quality-affecting procedures that BSC has issued since November 2005. Accordingly, the unavailability of a current QRM, to support this quality-oversight activity, is identified as a weakness related to BSC's Organizational Assurance, which should have ensured that the necessary documentation was complete and available at the initiation of the audit. The audit team also noted that, subsequent to the completion of the audit, a revised version of the QRM was provided to OQA, for review and acceptance. The DOE review of the revised QRM resulted in the identification of numerous errors. Two CRs, were written by DOE and BSC to document the poor quality of the QRM development and review.

As a result of this audit observation, the ORs also identified two OR Open Items that were provided to the Audit Team Leader at the conclusion of the audit. The first issue (OR Open Item 06-01), concerned a discrepancy in the definition of the term "requirement," in a BSC desktop instruction, which was inconsistent with the requirements for design-input control defined in QARD Section 3.2.1. The second issue (OR Open Item 06-02) involved the inconsistent use of quality-affecting document designators, which indicated inadequate corrective actions related to similar conditions documented in CR-3448.

3.6 OR Interactions on YMP Design-Control Topical Area

During February and March 2006, assigned OR reviewed the current YMP design control program and the planned actions to improve this area. This OR interaction was to verify that DOE has identified the correct problems, and is addressing appropriate corrective actions in this area. This review looked at YMP design-control activities that could impact the quality of information that would be contained in an LA, in order to identify program issues that could adversely affect the LA's quality and supporting information. Specific areas reviewed included: (1) project processes and mechanisms for design control-- including project management and technical direction, requirements flow-down, and configuration management; (2) basic design-control approach and mechanisms; (3) design-control CRs and root-cause reports; (4) management action and self-assessment team reports and planned actions; and (5) major requirements management program changes, tools, and their interfaces

The IPRT, CR, and other assessments identified many important and appropriate actions and recommendations to improve design control and requirements management processes, and indicated a proper integrated approach across project management and

technical disciplines. Completing the root-cause analyses, CR disposition implementation, and IPRT actions, etc., will challenge the available resources of skilled technical and management staff, particularly in areas of root-cause analysis and integrated regulatory and technical requirements management. NRC staff will continue to observe activities, in this area, to verify that DOE is assuring management priority and the tools and resources to implement and complete the actions required in the design-control/requirements-management area, and capture the improvements in the program, to prevent recurrence.

NRC staff noted that DOE had CRs or other precursors in 2003 and 2004, that identified the need for improvement in the design-control program, particularly requirements flow-down and management; in addition a need for improving engineering-design and safety-analyses interfaces was identified in early 2005 or before. Some actions were begun in these areas, but were not completed before these became major issues. NRC will continue to review DOE's actions, to develop an organizational structure and managerial approach that can identify, recognize, and move swiftly, to properly address, developing regulatory or technical issues, before they become major problems.

4.0 GENERAL ACTIVITIES

4.1 Meetings

- On February 1, 2006, staff from NRC and the CNWRA attended the Nuclear Waste Technical Review Board (NWTRB) meeting in Las Vegas, NV. At the request of the NWTRB, staff made a presentation on NRC's implementation of the U.S. Environmental Protection Agency's proposed Yucca Mountain Standard for the period of time after 10,000 years.
- On February 16, 2006, staff members from NRC, the CNWRA, and DOE, Office of Civilian Radioactive Waste Management, met in Las Vegas, NV, to discuss DOE and NRC activities at the Peña Blanca, Chihuahua, Mexico, site. Peña Blanca is being investigated as a natural analog to portions of the potential Yucca Mountain repository. DOE summarized its key results and presented information on ongoing seepage monitoring, dating of the age of the deposit, and radionuclide concentrations in groundwater at the site. It discussed a total system performance assessment of the analog site, that could be used to corroborate the DOE performance assessment of the potential Yucca Mountain repository. Logistics for working at the remotely located site and a DOE request for Center data to support DOE's seepage modeling were discussed.
- On March 21, 2006, NRC and DOE staff members held a Quarterly Management Meeting on the YMP, in Rockville, MD. DOE provided updates on the Project, including: (1) DOE's 2007 budget request; (2) near-term schedule; (3) USGS INFIL status; (4) lead-lab transition plan; (5) design activities and decisions; (6) Licensing Support Network status; (7) current QA issues; (8) CAP improvements; and (9) actions taken regarding the requirements flow-down and design-control problems discussed at the December 2005 Quarterly Management Meeting. DOE stated that it does not intend to submit a LA in fiscal year 2007, but plans to release a schedule in the June/July time frame, showing the projected submission date for the LA.

4.2 Other Activities During This Reporting Period

N/A - this reporting period.

**U.S. NRC ON-SITE LICENSING REPRESENTATIVES' TRACKING REPORT FOR OPEN
ITEMS FOLLOWED IN
OR REPORTS**

Table 1

OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEM	OPEN ITEM OR-REPORT NO.	
AOI-OCRWM-OQA-05-20-02	Revise procedure AP-3.13Q to reflect 10CFR63.21 requirements related to completeness of information necessary for LA review.	OR-05-03	
AOI-OCRWM-OQA-05-20-01	Procedural controls for "preliminary" classification of Engineering calculations will be revised to clearly define the designation of completed calculations suitable to support the requisite safety analysis.	OR-05-03	
AOI-YMSCO-ARC-02-12-01	Identifies the need for DOE OQA to ensure that procedure development and review process include a documented evaluation to verify compliance with the requirements of the YMP's QARD.	OR-03-01	
OR Open Item 06-02	Requirements Flow-Down and Procedural Adequacy Audit Observation: Involved the inconsistent use of quality affecting document designators which indicated inadequate corrective actions related to similar conditions documented in CR-3448.	OR-06-01	
OR Open Item 06-01	Requirements Flow-Down and Procedural Adequacy Audit Observation: Concerned discrepancy in the definition of the term "requirement" in a BSC desktop instruction, which was inconsistent with the requirements for design input control defined in QARD Section 3.2.1	OR-06-01	
OR Open Item 05-02	Pending Project response to the discovery of potential falsification of QA records - completion of second and third initiatives described in the work plan.	OR-05-03	
OR Open Item 05-01	Inconsistencies in the root cause statements developed by the root cause analysis team, specifically the root cause related to traceability and transparency issues. Pending resolution of the apparent discrepancies in the root cause analysis for CR-3235 identified in this Open Item.	OR-05-02	
OR Open Item 04-01	A concern regarding the safety analysis of the ground support system in the ESF.	OR-04-01	
OR Open Item 03-06	Based on review of CR-756, 12 quality-affecting procedures were approved without meeting the applicable QARD requirements.	OR-03-05	
OR Open Item 03-05	The continued use of unqualified software in quality-affecting technical products appears to be in conflict with the governing requirements of the implementing procedures and the QARD.	OR-03-04	
OR Open Item 03-04	With a tentative date of mid-June to evaluate CAR BSC(B)-03-©)-107, the RCD has not acted on this CAR in a timely manner and it has remained open for 4 months without resolution.	OR-03-03	
OR Open Item 03-03	An evaluation in DOE's progress in implementing corrective actions associated with CAR B.C.-01-C-001, concerning model validation, the OR reviewed TAPS (approx. 43 models). Based on the results, it could not be established if the evaluation criteria will result in the development of models with adequate confidence for the LA.	OR-03-02	
OR Open Item 03-02	During a review of the MII confirmation packages, it was identified that the action statement execution task descriptions and completion schedules for many of the reviewed pkgs had been modified without appropriate justification. Therefore, pending the resolution of this apparent deviation from a commitment to administer the MII in accordance with the requirements of AP-5.1Q, this issue is identified as this OR Open Item.	OR-03-02	

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OR Open Item 03-01	This Open Item is based on issues on separate DRs: (1) the effective resolution of concerns related to inadequate personnel training; 2) the failure to establish an effective transition plan; and 3) the evaluation of the SCWE issues.	OR-03-01	
OR Open Item 02-13	The current status of corrective & preventive actions associated with CAR No. BSC-02-C-01 revealed that not all corrective actions stated had been completed.	OR-02-05	
OR Open Item 02-12	Contrary to requirements of the QARD Supplement III 2.4.C, AP-SIII.2Q inappropriately allows for the use of unqualified data. BSC QA procedure change control program failed to identify this issue.	OR-02-05	
OR Open Item 02-11	Based on surveillance not identifying specific problems with software functionality for codes tested, 7, including NUFT, did not pass ITP and/or VTP surveillance.	OR-02-05	
OR Open Item 02-10	Pending appropriate evaluation and documentation of the design control attributes associated with requirements of 10 CFR 63.44 and 10 CFR Part 21.	OR -02-04	
OR Open Item 02-09	Pending revision of engineering procedures to include appropriate design verification considerations.	OR-02-04	
OR Open Item 02-08	The required performance of annual audits justification for delaying a scheduled audit of YMSCO for 3 months, with an additional extension, does not appear to be adequately supported. Deviation from requirement of sub-section 18.2.1E of the QARD.	OR-02-04	
OR Open Item 02-07	Model Validation Impact Assessment addressed the effect of inappropriately validated models on TSPA-SR. Many cases of impact assessments used TSPA-SR results to evaluate the local impacts. It's unclear how this practice evaluated the cumulative impact of all the models in question.	OR-02-01	
OR Open Item 02-06	Unqualified Data Impact Assessment - NRC staff identified unqualified data that could be replaced with qualified data for the performance assessment. For the risk-significant components, an evaluation of unqualified data replaced with qualified data would help determine if efforts should be undertaken to qualify the removed data.	OR-02-01	
OR Open Item 02-05	Provisions are in place that allow for model validation to continue past issuance of the documentation. The models used in the performance assessment should have adequate support for their representation at the time the performance assessment documentation is issued.	OR -02-01	
OR Open Item 02-04	A number of criteria have been developed related to various forms of review. If a review is relied on for model validation, it should be directed at validating the model and it should encompass the full body of information to the extent practical.	OR-02-01	
OR Open Item 02-03	More objective criteria (comparison to data not used in the development of the model), typically resulting in higher confidence in model validation are not distinguished from the more subjective, problematic criteria.	OR-02-01	
OR Open Item 02-02	Current process controls specify that one or more of nine criteria may be used to validate a model. All the criteria should increase confidence in the modeling process; some criteria do not appear to be appropriate for addressing whether the model is valid for its intended use.	OR-02-01	

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Table 1

OR Open Item 02-01	Failure to properly include the specific issues identified in the Concerns Program Final Report in the resolution process may result in not adequately addressing the original employee's concern.	OR-02-01	
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